510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Name, Address, Phone and Fax number of the Applicant

Guidant Corporation
Cardiac Surgery Group
10600 North Tantau Avenue
Cupertino, CA 95014

Telephone: (408) 366-3261
Fax: (408) 366-3205

B. Contact Person

Anne Schlagenhaft
Regulatory Affairs Associate

C. Date Prepared

January 12, 2001

D. Device Name

Trade Name: Guidant Axius™ Coronary Shunt
Classification Name: Vascular Clamp

E. Device Description

The Guidant Axius™ Coronary Shunt is a disposable device that consists of a coil reinforced polymer shaft with a seal on each end and tapered tips. The seals contact the vessel wall, thus occluding the artery proximal and distal to the arteriotomy. The Guidant Axius™ Coronary Shunt is selected according to the outer diameter of the seals and is available in various sizes to fit a range of vessel diameters. There is a hole in the tapered tip ends that allows for blood flow through the shunt shaft and beyond the arteriotomy. A polyester thread is attached to the Guidant Axius™ Coronary Shunt in the middle of the shaft. A radiopaque tab

attached to the thread is used to aid insertion and removal of the Guidant Axius™ Coronary Shunt.

F. Intended Use

The Guidant Axius™ Coronary Shunt is designed to reduce blood in the operative field by temporary occlusion of the artery and to provide blood flow distal to an arteriotomy. The Guidant Axius™ Coronary Shunt is not an implant and is removed prior to completion of the anastomosis.

G. Substantial Equivalence

The 1.0 and 1.25 mm sizes of the Guidant Axius™ Coronary Shunt are substantially equivalent to the sizes currently manufactured. The current sizes of the Guidant Axius™ Coronary Shunt were cleared by the Food and Drug Administration under K970638 on October 3, 1997. The design of the 1.0 and 1.25 mm sizes of the Guidant Axius™ Coronary Shunt is identical to the current Shunt sizes. The 1.0 and 1.25 mm sizes of the Shunt are composed of the same materials as the currently available sizes. The smaller 1.0 and 1.25 mm sizes of the Shunt are substantially equivalent in intended use, design, materials, manufacturing processes, technological characteristics, and components to the currently available sizes of the device.

H. Device Testing Results and Conclusion

All necessary testing was performed on the Guidant Axius™ Coronary Shunt to ensure that the product is substantially equivalent to the predicate device and to ensure that the modified dimensions do not have a significant effect on safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2001

Guidant Corporation
Cardiac & Vascular Surgery Group
c/o Ms. Anne Schlagenhaft
Regulatory Affairs Associate
10600 N Tantau Avenue
Cupertino, CA 95014-0739

Re: K010117
Trade Name: Guidant Axius™ Coronary Shunt
Regulatory Class: II (Two)
Product Code: DXC
Dated: January 12, 2001
Received: January 16, 2001

Dear Ms. Schlagenhaft:

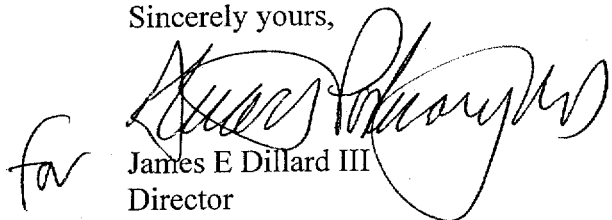
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 010117

Device Name: Guidant Axius™ Coronary Shunt

Indications For Use: The Guidant Axius™ Coronary Shunt is designed to help reduce blood in the operative field by temporary occlusion of the artery and to provide blood flow distal to the arteriotomy. The Axius™ Coronary Shunt is not an implant and is removed prior to completion of the anastomosis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

3/29/1

Division of Cardiovascular & Respiratory Devices
510(k) Number K010117